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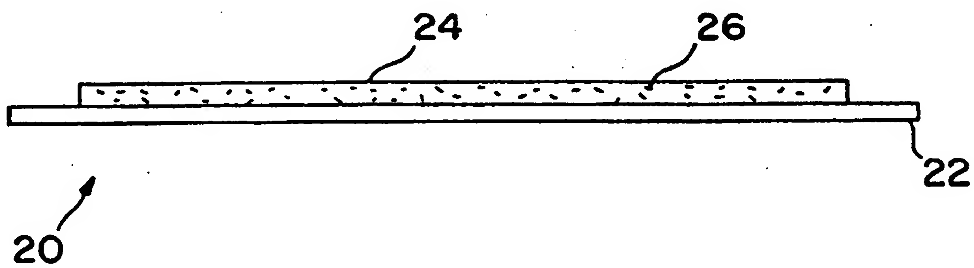

(57) Abstract

A modified membrane material including a conductive surface (24) which may be used for a variety of medical or other applications, is provided. Various devices can be formed of the conductive surface materials including tubes, probes, catheters, and the like. Activation of the conductive surface (24) such as by connection to a suitable energy source enables electrical current to be passed into a body region, or to a device (e.g., container) useful in holding, and/or treating other materials.

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ELECTRICALLY CONDUCTIVE MEMBRANE SUITABLE FOR MEDICAL USES

Field of the Invention

The present invention generally relates to membranes useful in connection with a variety of medical applications, and more particularly to membranes that include conductive material, which may be coated onto or integral to the membranes.

Background of the Invention

Conductive surfaces have several applications in medicine. For example, cardiac pacemakers have conductive surfaces that transfer electrical pulses to the heart to stop unwanted electrical activity in the conduction fibers of the heart. Additionally, it is well known that electrical fields applied to nerves, muscles, vessels and the like can stimulate the corresponding nerves, muscles, vessels or other tissue.

Recently, new, potential, uses for the conduction of electricity in medical contexts have been developed. For example, in *Shocking Treatment Proposed for AIDS. (zapping the AIDS virus with low-voltage electric current)*, 139 SCIENCE NEWS 207 (1991), methods to reduce infectivity of viruses by applying a current, *e.g.* in the range of about 50 to 100 μ amps, to white blood cells containing the virus exist. The current is believed to affect the virus such that production of enzymes crucial to virus reproduction is inhibited.

Application of an electric pulse to fluids to sterilize the fluid is also known. In particular, Viazurek et al., *Effect of Short HV pulses on Bacteria and Fungi*, 2 EEE TRANSACTIONS ON DIELECTRICS AND ELECTRICAL INSULATION 418 (1995) discloses use of electrical pulses to sterilize consumable fluids, which may either be ingested by or inserted into a patient.

Another medical application is the electrical sterilization of biofilms (*e.g.*, biofilms which form on a dialysis membrane away from an electrode). Wellman et

al., *Bacterial Biofilms and the Bioelectric Effect*, 40 ANTIMICROB AGENTS CHEMOTHER 2012 (1996) discloses increased efficiency of sterilizers, such as antibiotics and biocides, by the addition of an electric field. Thus, in the presence of an effective electrical field, less sterilizer is required to kill unwanted bacteria and may therefore reduce the risk of antibiotic resistance.

Application of electrical current may also be used to simulate growth of certain bacteria. As disclosed in *Using Electricity to Kill Bugs*, 18 EPRI JOURNAL 4 (1993), this technique may be used for, *inter alia*, production of genetically engineered substances. Alternatively, this technique could be used to breed beneficial bacteria within a body. Additionally, it is thought that small electrical fields can attract or repel various pathogens or bacteria from an area which includes the electrical field.

Use of electricity to generate local heat is also known. In this regard application of localized heat within a body can have therapeutic effect. Accordingly, placing resistive or conductive materials within the body and passing a current through such materials to generate heat to the body regim of interest can have therapeutic value. In addition, extreme local heat may be used to cauterize or remove unwanted material. Removal of unwanted material is assisted by destroying, burning, or reducing a volume of unwanted material, making removal of such material through a relatively small opening possible. For example, unwanted plaque or cholesterol may be removed using this technique.

The above and other medical applications generally are accomplished by electrically connecting sensors inside a body to instruments outside a body, or by the invasive insertion of rigid electrodes into a patient, or by the addition of electricity to a device, such as a container, filled with a material to be treated. Each of these methodologies have various drawbacks.

For example, invasive insertion of rigid electrodes is problematic because, *inter alia*, the insertion may increase the risk of infection to the patient. Additionally, insertion of a rigid electrode may cause discomfort to the patient during and/or after insertion.

Similarly, medical applications involving the external use of electricity (for example, to grow or inhibit growth of certain bacteria) often require multiple

components, for example, an electrode which is attached to a device (*e.g.*, a container) to hold the material to be treated. As a result, the apparatus is typically complex and, because of the extra components, extra surface area must be sterilized prior to use, thus, tendering increased costs associated with the procedure.

Summary of the Invention

The present invention provides a biocompatible medical device having a flexible, conductive membrane which addresses the aforementioned drawbacks of presently known conductive surfaces used for medical application of electricity to a body or other material to be treated.

While the way in which the present invention addresses the drawbacks of the prior art will be described in greater detail below, in general, in accordance with various aspects of the present invention, a conductive surface is provided which can be formed into a variety of different devices. In its broadest sense, however, the present invention relates to the conductive surface and the manner by which such a surface is formed.

In accordance with various aspects of the present invention, such a surface is formed by application of a conductive material by deposition, impregnation and/or mechanical attachment to a flexible substrate. This material can then be formed into a variety of devices ranging from a conductive sheet, a conductive tube, probes, catheters and the like.

In accordance with various aspects of the present invention, the flexible substrate preferably comprises a polytetrafluoroethylene (PTFE) resin or modified PTFE resin. In addition, preferably, the conductive material comprises a metal.

In accordance with another aspect of the present invention, a probe for insertion into a body orifice is provided. The probe comprises a tube, a modified PTFE membrane, a conductive surface and a guide assembly. The membrane and conductive surface are suitably attached to the guide assembly and inverted over the first open end of the probe with the majority of the membrane being contained within the lumen of the tube. When the probe is inserted into a body orifice, the membrane

and conductive surface are withdrawn from the tube open end and the membrane and conductive surface are interposed between the tube and the body orifice.

Brief Description of the Drawing Figures

A more complete understanding of the present invention may be derived by referring to the detailed description and claims when considered in connection with the Figures, where like reference numbers refer to similar elements throughout the Figures, and:

Figure 1 is a side view of a conductive surface in accordance with one embodiment of the present invention;

Figure 2 is a side view of a further embodiment of a conductive surface in accordance with the present invention;

Figure 3 is a perspective view of yet a further embodiment of a conductive surface in accordance with the present invention;

Figure 4 is a perspective view showing the surface of Figure 3 as it has been formed into a tube-like device;

Figure 4A is an end view of the tube of Figure 4 taken along the lines A-A of Figure 4;

Figure 4B is a cross-sectional view of the tube of Figure 4 taken along the lines B-B of Figure 4;

Figure 5 is a perspective view of a further embodiment of a conductive surface in accordance with the present invention;

Figure 6 is a perspective view of a tube which has been formed from the conductive surface of Figure 5;

Figure 6A is a cross-sectional view taken along the lines A-A of Figure 6;'

Figure 6B is a cross-sectional view of a tube in accordance with another embodiment of the present invention;

Figure 7 is a perspective view of a further embodiment of a conductive surface in accordance with the present invention;

Figure 8 is a perspective view of a still further embodiment of a conductivbe surface in accordance with the present invention;

Figure 8A is a cross-secitonal view of a conductive surface of Figure 8;

Figure 9 is a perspective view of a tube formed of the conductive surface of Figure 7;

Figure 9A is a perspective view of a further embodiment of a tube formed of the conductive surface of Figure 7.

Figure 9B is a cross-sectional view of still a further embodiment of a tube formed of a conductive surface in accordance with the present invention;

Figure 10 is a perspective view of yet another embodiment of a tube formed of a conductive surface in accordance with the present invention;

Figure 11 is a perspective view of a still further embodiment of a tube formed of a conductive surface in accordance with the present invention;

Figure 12A shows a probe for insertion into a body orifice including an unfolding membrane provided with a conductive surface in accordance with the present invention;

Figure 12B shows a further view of the probe of Figure 12A showing the unfolding of the conductive surface and membrane;

Figure 13 is a perspective view of a further embodiment of a probe in accordance with the present invention;

Figure 14 is a perspective view of a still further embodiment of a probe in accordance with the present invention;

Figure 15 is a perspective view of a pouch formed of a plurality of conductive surfaces in accordance with the present invention;

Figure 16 is a perspective view of a multi-lumen tube formed of at least one conductive surface in accordance with the present invention;

Figure 17 is a perspective view of a conductive surface in accordance with the present invention utilized as a stent covering;

Figure 18 is a perspective view of a further embodiment of the conductive surface in accordance with the present invention used as a stent covering; and

Figure 19 is a perspective view of a tube formed of the conductive surface in accordance with the present invention which is part surrounded by a further protective sheath.

Detailed Description of Preferred Exemplary Embodiments

The present invention relates generally to devices, which can be formed from flexible materials having at least one conductive surface, which devices may be useful in various medical applications. Such applications include a variety of medical procedures, applications, and thus, the devices of the present invention can be used for internal and/or external procedures to a body or for treatment of other materials. For example, devices in accordance with various aspects of the present invention may be used to apply localized heat or an electrical field to a particular region of a body or other material to be treated.

Referring now to Figure 1, a conductive surface 10 in accordance with one aspect of the present invention is shown. Surface 10 suitably includes a flexible material 12 which is configured to receive a conductive path 14. Preferably, path 14 covers at least a portion of material 12. As described in greater detail hereinbelow, surface 10 is configurable to be formed in a variety of geometric configurations to form a device, which device may be suitable for various medical applications.

Flexible material 12 may include any material which is biocompatible and capable of receiving conductive path 14, yet which is flexible enough to perform the desired functions. As such, the materials which can be utilized in the context of the present invention to form flexible material 12 can vary from application to application. However, in accordance with a preferred aspect of the present invention, flexible material 12 comprises a polytetrafluoroethylene (PTFE) resin, a modified PTFE resin or combinations thereof. In accordance with a particularly preferred aspect of the present invention, material 12 is preferably formed from a sintered PTFE film formed by skiving it off a billet to a desired thickness. Preferable PTFE billets may comprise Hoechst TMF 1700 or TMF 1702, or other chemical compounds available from DeWall Industries of Saunderstown, RI under the names DW/200 and DW/220, respectively, or under other names as may be obtained from other processors. Such materials typically comprise a modified PTFE resin, which include a PTFE polymer modified by the addition of a small amount of perfluoro propyl vinyl ether (PPVE). Other modified PTFE resins, such as those available from DuPont under the name Mitsui-DuPont TG 70-J, may also be utilized. Additionally, PTFE homopolymers or

copolymers with comonomers like PPVE, PFA and the like may be used in the context of the various aspects of the present invention. In general, it should be appreciated that other PTFE films and/or resins may also be used to form devices in the context of the present invention as are now known or hereafter devised by those skilled in the art.

In general, the aforementioned PTFE resin films are such that interfacial fusion is possible; that is, as will be appreciated by those skilled in the art, the materials can be heat sealed upon themselves. As will be described in greater detail hereinbelow, the flexible materials useful in the context of the present invention are suitably formed into devices which can be utilized in various medical applications. Such materials which can be used to form flexible material 12, may be processed as set forth in, for example, U.S. Patent No. 5,711,841 issued January 27, 1998, to Jaker, or the related Patents Nos. 5,531,717 issued July 2, 1996 to Feliziani et al., and/or 5,676,688 issued October 14, 1997 to Jaker et al. The entire contents of each of the '841, the '717 and the '688 patents are hereby incorporated into this application by this reference. Such processing may include, for example, elongation, tensilization, sintering, etc.

With continued reference to Figure 1, conductive path 14 in accordance with various aspects of the present invention is preferably applied to material 12. Such application may be accomplished through a variety of methodologies. For example, path 14 may be deposited upon material 12. Alternatively, path 14 may be adhered to material 12 in any conventional fashion as is now known or hereafter devised by those skilled in the art. In this regard, natural attachment of path 14 to material 12 may be accomplished by virtue of the chemical and/or mechanical composition of the components. For example, static or other adhesive forces may be sufficient in certain instances to secure the material which comprise path 14 to flexible material 12.

In general, preferably conductive path 14 is formed of a material which enables electrons to be conducted therewithin. In this regard, conductive path 14 suitably comprises any electrically conductive material such as metals, combinations of metals and/or the like. In accordance with the preferred aspect of the present invention, and

with continued reference to Figure 1, conductive path 14 is formed of a material which comprises gold, silver, copper, nickel, zinc or any combinations thereof.

With continued reference to Figure 1, path 14 may be suitably deposited onto flexible material 12. In accordance with preferred aspects of this embodiment of the present invention, conductive path 14 is formed by vapor coating, plasma coating, sputter coating, ion coating, and/or wet plating a desired conductive material (*e.g.*, a metal) onto flexible material 12. For example, conductive path 14 may be formed on flexible material 12 by applying an electrical bias to or proximate material 12 and causing conductive ions (*e.g.*, metal ions) to deposit onto material 12. As will be appreciated by those skilled in the art, application of such an electrical bias during deposition of the material forming path 14 may increase adhesion between path 14 and flexible material 12, etc.

Preferably materials selected for use as flexible material 12 comprise, as previously noted, a biocompatible material. Such materials generally have a composition which may include micro fissures or cracks, the presence of which aid in bonding between flexible material 12 and conductive path 14.

In alternative embodiments of the present invention, some of which will be described in greater detail hereinbelow, conductive path 14 may be applied to material 12 using a snap ring, or sandwiching conductive layer 14 between two layers of flexible material 12, etc.

With continued reference to Figure 1, flexible material 12 may be suitably prepared for deposition of conductive material to form path 14 in a variety of ways, as will be appreciated by those skilled in the deposition art. For example, in accordance with a preferred embodiment of the present invention, material 12 is treated with an etchant such as Gore Tetra-Etch®, is then preferably rinsed with isopropyl alcohol and distilled or deionized water to, among other things, remove fluorine residue from a surface of material 12, and is then dried prior to conductive material deposition. To promote adhesion, the treatment, rinse, and deposition processes are preferably performed in a clean environment and away from excess ultraviolet light.

In accordance with various aspects of the present invention, flexible material 12 preferably has a thickness on the order of less than 0.005 inches thick. As will be described in greater detail below, membranes/layers of such a thickness can be easily formed into a variety of suitable devices useful in a variety of medical applications. It should be appreciated, however, that conductive surface 10 may have thickness in excess of 0.005 inches. However, preferably the thickness of conductive surface 10 is in the range from about 0.0005 inches to about 0.005 inches. With continued reference to Figure 1, in accordance with this embodiment of the present invention, conductive path 14 formed by a deposited layer preferably has a thickness in the range of about 10 to 100 angstroms.

Referring now to Figure 2, a conductive surface 20 includes a flexible membrane 22, which is configured for receipt of a conductive layer 24. In accordance with this alternate embodiment of the present invention, conductive layer 24 includes suitably a plurality of particles of conducting material 26, such that layer 24 is conductive. As will be described hereinbelow, layer 24 may be used alone or in connection with flexible membrane 20, such as is shown in Figure 2. When used in connection with membrane 20, layer 24 may be affixed to membrane 20 using any suitable means. In accordance with preferred aspects of this embodiment of the present invention, layer 24 is attached to membrane 22 by spot welding the layers together. Other mechanical or chemical attachment mechanisms or devices may, however, also or in the alternative, be used.

In accordance with preferred aspects of this embodiment of the present invention, flexible membrane 20 may include any biocompatible, flexible material that can receive conductive layer 24, such as by spot welding. For example, the aforementioned PTFE resins may be used to form conductive layer 24. Materials or surfaces formed of such resins are substantially biocompatible, and the material or surface can be impregnated with conducting material 26. Conductive material 26 may be any material that enables electricity to be conducted through a portion of layer 24. Preferably, conducting material may include particles of metal, carbon and/or the like. Iron or iron-like particles have been found to be particularly preferred.

Preferably, and as will be described in greater detail below, layer 24 comprises a modified PTFE resin of the type previously described which is impregnated with suitable conducting material. In the context of this embodiment of the present invention, preferably layer 24 is fully impregnated with the conducting material. Stated in another way, conducting material 26 is fully dispersed throughout layer 24 such that, in general, layer 24 is fully conducting. As will be appreciated, and as will be described in greater detail below, in accordance with various other aspects of the present invention, portions of layer 24 may be formed to be conducting such as by impregnating the PTFE resin making up layer 24 about only a portion of the layer.

For example, with reference now to Figure 3, a conductive surface 30 may be provided which includes a flexible substrate 31 having a first edge 32 and a second edge 33. Substrate 31 is suitably provided with a conductive path 34 which spans the length of substrate 31 between respective edges 32 and 33. Conductive path 34 may be suitably formed in substrate 31 such as by impregnation. In this regard, and as shown best in Figure 3, conductive particles may be impregnated into a portion of substrate 31 through the use of any conventional or hereafter devices impregnation technique. Preferably, as shown in Figure 3, impregnation of conductive materials in this fashion causes only a portion of one of the sides of substrate 31 to exhibit conductive path 34. It should be appreciated, however, that such conductive path could span the thickness of substrate 31, or alternatively, span various depths between the surface impregnation generally shown in Figure 3 to the entirety of the thickness of substrate 31.

Referring now to Figure 4, a conductive surface 30 is suitably configurable to form a tube 34. As will be appreciated, tube 34 may be formed in a variety of ways. For example, edges 32 and 33 may be attached using an appropriate adhesive, spot welding or the like. Preferably, tube 34 is formed by joining edges 32 and 33 and forming a heat seal at the junction by applying heat proximate or directly to the junction of edges 32, 33. Tube 34 includes a conductive path 36 spanning the length of tube 34. In accordance with a further preferred aspect of this embodiment and as shown, for example, in Figure 4B, path 44 suitably spans all or most of the length of tube 34. As previously noted, in accordance with a preferred aspect of this

embodiment of the present invention, conductive path 46 extends only partially into flexible substrate 31.

Tube 34, as so configured, suitably enables the conduction of electricity through conductive path, when conductive path is suitably connected to an appropriate power supply (not shown). Suitable power supplies may include voltage current or other electrical generating sources.

It should be appreciated that various configurations of conductive surfaces can be formed in the context of the present invention. For example, and referring now to Figure 5, a conductive surface 40 may suitably comprise a flexible substrate 41 incorporating a widthwise oriented conductive path 42. In accordance with various aspects of this embodiment of the present invention, flexible substrate 41 is suitably provided to exhibit respective ends 43, 44 and respective edges 45, 46. Preferably, as show, conductive path 42 traverses between edges 43 and 44.

Conductive surface 40, like conductive surfaces 30, 20 and 10, is suitably configurable to form a suitable device. For example, and with reference now to Figure 6, surface 40 may be suitably formed into a tube 47. For example, edges 43 and 44 may be suitably joined to form tube 47. As noted above, edges 43 and 44 may be attached in a variety of ways, and are preferably attached to each other by heat sealing edges 43, 44 together. Tube 47, as shown, includes a circumferential conductive path, namely, conductive path 42. Conductive path 42 may be energized through any suitable means, such as through the use of wiring extending through the lumen 48 of tube 47 or any other suitable manner. While as shown in Figure 6A, conductive path 42 extends only partially into the surface of substrate 41 used to form tube 47. In accordance with various other aspects of this embodiment of the present invention, path 46 may include a radial extension 49 which extends from lumen 48 to the outermost surface of tube 47. In this manner, electrical connections can be made through the lumen. Alternatively, and in accordance with various other aspects of this embodiment of the present invention, connecting wires (not shown) may be passed along the exterior surface of tube 47.

While tubes 34 and 47 have been illustrated as including respective conductive paths 36 and 42 on the exterior portion of the tubes, those skilled in the art will

appreciate that other configurations may suitably be formed. For example, the conductive paths may be formed on the interior portion of the tubes. Alternately, the conductive paths may be formed on the exterior portion of the tubes, such as shown in Figures 4 and 6, with such tubes thereafter being inverted (i.e., turned inside out) such that the conductive material is then oriented on the inside of the tubes. Similarly, the conductive paths may be formed on the interior of such tubes, and the tubes can be inverted such that the conductive paths are then oriented on the exterior of the tubes.

From the disclosure thus far provided, it should be appreciated that various conductive path configurations may be suitably provided in the various conductive surfaces of the present invention. Referring now to Figure 7, a conductive surface 50 having a multi-component conductive path 41 may also be formed. As shown, conductive surface 50 suitably evidences a first edge 52, a second edge 53, a first end 54, and a second end 55. Further, surface 50 preferably evidences a top 56 and a bottom 57. In accordance with a preferred aspect of this embodiment, path 51 suitably includes portions 51A and 51B, wherein portion 51A preferably runs between edges 53 and 55 and portion 51B preferably runs substantially between edges 52 and 54. Portions 51A and 51B are preferably electrically connected, such that, for example, current applied to portion 51A flows to portion 51B. As with the conductive portions of the various conductive surfaces previously described, conductive portions 51A and 51B are suitably formed by impregnating conductive particles into the body of flexible substrate 50. For example, with reference to Figures 8 and 8A, in accordance with one aspect of this embodiment of the present invention, portion 51A prime may extend throughout the thickness of substrate 50, whereas portion 51B may extend only about a portion of the thickness of substrate 50. It will be appreciated that various other combinations are also possible.

Conductive surface 50 may be suitably formed into a device, such as a tube such as is shown in Figure 9.

Tube 58 is preferably formed by joining and attaching edges 53 and 55 of surface 50, such as by heat sealing or the like. As shown in Figure 8, conductive path 51 may be configured on the exterior of tube 58, or as shown in Figure 8B, on

an interior portion of tube 59. As should be apparent, to form tube 59, edges 53 and 55 are joined and attached such that top 56 forms the central lumen of the tube.

With reference now to Figure 9, various other modifications in the configuration of conductive path 51 may be made. For example, as shown, portion 51B of conductive path 51 may not extend about the entire circumference of tube 58, but rather, portion 51B may extend only over a desired arc.

While in connection with conductive surfaces 30, 40 and 50, the respective conductive paths have been described herein as being formed through the impregnation of conductive particles into the substrate, the conductive paths may be formed in any convenient manner. For example, the conductive paths may be applied to all or a portion of a tube-like structure. In this regard, and with reference now to Figure 10, a tube 60 may be formed from a flexible material 62 and a conductive ribbon 64 attached thereto in any suitable manner. For example, ribbon 64 may be attached about its length to tube 60, or attached only as portions, or even, attached only at one end or one portion thereof. In accordance with a preferred aspect of this embodiment of the present invention, ribbon 64 is attached to material 62 by depositing ribbon onto material 62 or spot welding ribbon 64 to material 62. Although not shown in Figure 10, ribbon 64 may extend beyond the length of tube 60. Preferably, in accordance with this aspect of the present invention, tube 60 is formed of a flexible substrate material, for example, of the type used to form tube 34.

In accordance with yet another embodiment of the present invention, a tube 70 is provided which is formed from a flexible material 72 fully impregnated with conductive particles 74. For example, flexible material 72 may be formed in a manner similar to that described hereinabove in connection with conductive surface 24 shown in Figure 2.

The various tubes and conductive surfaces herein described can be used in a variety of manners in accordance with various aspects of the present invention. For example, one or more of the tubes may be used in connection with forming a probe for insertion into a body orifice. Various non-contaminating probes and methods of making and using the same are disclosed in the aforementioned '717 and '841 patents. Such probes may be configured for a variety of medical uses, such as a

urinary catheter, a coronary catheter, a drainage tube, a medical probe, an introducer and/or the like. In any of those configurations, the unfolding membrane which enables the probe to be substantially non-contaminating can be provided with a conductive surface of the type described herein to offer additional advantages.

Referring now to Figures 12A and 12B, a probe 80, for interion into a body orifice preferably includes a tube 81, an unfolding membrane 82, a conductive ribbon 83 and a guide ring assembly 84.

As shown, preferably a major portion of membrane 82 and conductive ribbon 83 are initially disposed inside the lumen of tube 81 with a minor portion of such materials extending outwardly over the tip of tube over the leading edge of tube 81, the portions extending outside of tube 81 being attached to guide ring assembly 84. As shown, preferably ribbon 83 is suitably attached to a power supply 85, which power supply enables current or other electrical energy to be passed through to conductive ribbon 83. With reference to Figure 12B, as probe 80 is inserted into a body orifice, for example, the urethral canal of a human or animal, or a body port or other orifice, membrane 82 and conductive ribbon 83 are suitably unfolded out of tube 81 and disposed along the outside surface of tube 81 interposed between tube 81 and the body orifice.

Inasmuch as the use and operation of probes 80 such as are briefly described herein are described in greater detail in connection with the aforementioned '717 and '814 patents, they will not be further described in this application.

Various other probe-type configurations can also be formed. With reference now to Figure 13, a probe assembly 90 for use in connection with a tube 81 may be further provided with an external sheath material which is attached over membrane 82 and ribbon 83. Such a protective sheath may further provide protection of ribbon 83 and/or provide a barrier between ribbon 83 and the body orifice. Assembly 90 can be used in connection with a tube 81 in a manner similar to that described in connection with probe 80 shown in Figures 12A and 12B.

The various conductive surface materials in accordance with various aspects of the present invention may also be used in connection with the formation of a variably inflatable medical device, such as that as shown in U.S. Patent No.

5,676,688. Specifically, the non-contaminating searcher introducer/dialater disclosed in the '688 patent includes a variably inflatable tubular balloon membrane. In connection with the present invention, the tubular baloon membrane may be formed of a conductive surface material, for example, such as described in connection with Figures 4, 6, 8, and/or 10. Alternatively, and as shown in Figure 14, a conductive ribbon may be placed interiorly of the double-walled balloon membranae useful in connection with that particular device. As shown in Figure 14, a non-contaminating device 100 preferably includes an introducer tube 102, a membrane 104, a guide 106, a conductive ribbon 108, and a retaining device 110. As shown, membrane 104 preferably comprises a double tube configuration including an inner tube and an outer tube. Ribbon 108 is preferably placed between inner tube and outer tube or alternatively may be placed along the external surface of the tube, which is caused to unfold through use of introducer/dialater 100.

It should be appreciated that other probe configures also may be formed in accordance with various aspects of the present invention. From the description herein provided, various modifications and other configurations will likely be apparent to those skilled in the art. The previous probe examples have been provided for illustrative purposes only and not as a limitation of the type on the type of probe which can be formed in accordance with the present invention. In general, in any case wherein which a conductive surface can be useful, aspects of the present invention may be employed.

The various conductive surface materials herein described may also be utilized to form additional devices.

With reference now to Figure 15, a conductive surface of the type shown in Figure 5 may be joined to a non-conductive surface or yet another conductive surface to form a pouch 110. As shown, pouch 110 preferably includes a first material 111 and a second material 112. Materials 111 and 112 are suitably joined along three sides thereof, such as by heat sealing, to form an edge 113 that extends therearound. As shown, sheet 111 may be suitably provided with a conductive path 115. Conductive path 115, when suitably connected to an appropriate power supply or other activation source, may be suitably utilized to heat or otherwise send an

electrical charge to the materials contained within pouch 110. Various uses of such a configuration will be apparent to those skilled in the art.

Various other devices may be formed of the conductive surface materials herein described. For example, the various devices which are disclosed in co-pending United States Patent Application Serial Number 08/911,496 by the same inventors may be augmented with the conductive surface materials disclosed herein. Exemplary devices are discuses herein below.

Referring now to Figure 12, a tube 120 in accordance with a further embodiment of the invention may be formed of four layers of material, a tube 120 may be formed of four layers of membrane material, namely respective layers 121, 122, 123 and 124, one or more of which may comprise a conductive surface material in accordance with the present invention. Preferably, layers 121, 122, 123 and 124 are suitably sealed at, for example, respective edges 125 and 126 to form longitudinal seals about the length thereof. Such seals are suitably formed by, for example, heat-sealing as described hereinabove. As will be readily appreciated from Figure 17, tube 120 provides a lumen between adjacent layers of material, namely a lumen 127 between juxtaposed layers 121 and 122, a lumen 128 between juxtaposed layers 122 and 123, and a lumen 129 between juxtaposed layers 123 and 124. In accordance with a particularly preferred aspect of this embodiment of the present invention, one (or more) of the layers is suitably provided as a conductive surface. For example, surface 121 may include a conductive path 130 provided along a length thereof. It should be appreciated that various configurations of multi-lumen tubes having one or more layers formed in whole or in part of a conductive surface material in accordance with the present invention may be made, and thus are within the scope of the present invention.

In accordance with various other embodiments of the present invention, the conductive surface materials disclosed herein may be suitably used as coverings and/or coatings for various other devices. For example, in the context of various surgical applications, stents are used to separate tissues, organs or other members for a variety of medical purposes. Such stents may be formed of plastic, metal or other materials and may exhibit a multitude of configurations. In accordance with

various aspects of these embodiments of the present invention, the conductive surface materials disclosed herein are useful in covering such stents to render them more useful and offer significant advantages over currently available stents.

Referring now to Fig. 17, a stent structure 140, suitably comprising a frame member 142, typically formed of wire or other material, is configured to exhibit a number of openings and preferably is wound into a bundle, the bundle being covered by a conductive surface material 144 in accordance with the present invention. Membrane material 144 may be suitably secured to stent 142 by, for example, wrapping material 144 around the end of the stent and heat-sealed upon itself to suitably secure that end of the membrane material to the end of the stent. Alternatively, a tab configuration (not shown) can be formed in the piece of material to attach the material to the stent. Material 144 is provided with a conductive path 146, which when activated may provide heat to that portion of the stent.

Alternative stent covering configurations may also be employed in connection with the present invention. Referring now to Figure 18, a further embodiment of a stent covering in accordance with the present invention is shown. For example, a suitable stent structure 220 is formed by a frame 222 optimally configured to exhibit a plurality of openings. Frame 222, as shown, includes at least a first end frame member 224 and a second end frame member 226. In accordance with this aspect of this embodiment of the present invention, a suitably sized and dimensioned piece of conductive surface membrane material 230 having a first end 232 and a second end 234 is suitably wrapped around stent frame 222. Preferably, and as shown in Figure 18, first end 232 is suitably wrapped around member 224; similarly, second end 234 is suitably wrapped around member 226. Preferably, the respective ends of sheet 230 are suitably sealed to secure sheet 230 to stent frame 222. While various securement techniques may be used, spot welding techniques, such as through the application of heat at a particular spot along sheet 230 suitably are used. For example, as shown in Figure 18, end 234 is tucked under frame member 226 and a suitable spot weld may be applied at point A. Similarly, end 232 is wrapped around member 224 and may be preferably folded back over itself and then spot-welded, for example, at location B to securely hold end 232 to stent frame 222. Conductive

surface membrane material 230 is suitably provided with a conductive path 240 which extends about the length of material 230 suitably about and around stent frame 226. Activation of path 240 suitably causes heating of the region and thus of the stent.

Various other configurations may be formed of the conductive surface materials disclosed in here. For example, various flexible tubes may be combined for certain purposes. For example, with reference now to Figure 19, a conductive tube 230, of the type shown in Figure 10, may be provided with a protective sheath 232 as shown. Sheath 232preferably comprises a flexible material, preferably a PTFE resin material which may be provided in the form of a conductive or non-conductive sheath. For example, sheath 232 may be formed of a conductive surface material such as layer 24 set forth in Figure 2. Alternatively, sheath 232 may be non-conductive and be simply used in connection with conductive tube 232 It will be understood that the above description is of preferred exemplary embodiments of the present invention, and that the invention is not limited to the specific forms shown and described herein. For example, some or all of the components may be modified and alternative configurations which are apparent to those skilled in the art can be made and some various modifications may be made in the design and arrangements of the elements within the scope of the present invention as expressed in the appended claims.

Various configurations and medical devices disclosed herein as being in accordance with the present invention are shown for illustration only, and are not meant to limit the configurations or applications of the present invention to any particular manner.

CLAIMS

We Claim:

1. A device useful in connection with various medical applications, the device comprising:

a flexible material including a conductive path,

wherein said flexible material is configurable to form the device.

2. The device of claim 1, wherein the flexible material comprises a modified polytetrafluoroethylene (PTFE) resin.

3. The device of claim 2 wherein said flexible material comprises a PTFE resin modified with less than about five weight percent of per fluoro propyl vinyl ether, which resin is centered and skived from a billet.

4. The device of claim 2 wherein said conductive path comprises conductive particles which are impregnated into said flexible material.

5. The device of claim 2 wherein said conductive path is formed by depositing conductive material onto said flexible material.

6. The device of claim 2 wherein said conductive path comprises a conductive ribbon attached to said flexible material.

7. The device of claim 4 wherein said device is a tube.

8. The device of claim 4 wherein said device is a pouch.

9. The device of claim 4 wherein said device is a multi-lumen tube.

10. The device of claim 7 wherein said tube includes a first end, a second end, and a lumen spanning therebetween, said conductive path being oriented axially about the inner or outer surface of said tube.

11. The device of claim 7 wherein said tube comprises a first end, a second end, and a lumen spanning therebetween, wherein said conductive path is oriented circumferentially about an end of said tube.

12. The device of claim 11 further comprising an outer protective sheath formed of a flexible material.

13. A probe for insertion into a body orifice comprising:

a tube having first and second open ends;

a modified polytetrafluoroethylene membranae;

a conductive ribbon;

a guide assembly;

wherein said membrane and said ribbon are suitably attached to said guide assembly and inverted over said first open end of said tube, the majority of said membrane and said ribbon being contained within the lumen of said tube;

wherein as said tube is inserted into the body orifice, the membrane and ribbon are withdrawn from said tube first open end;

wherein an electrical current is provided to said conductive ribbon.

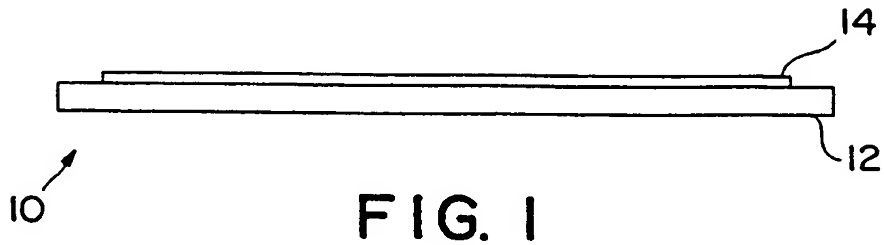

FIG. 1

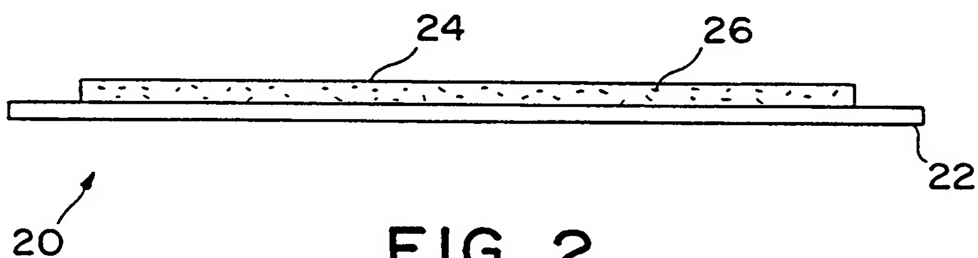

FIG. 2

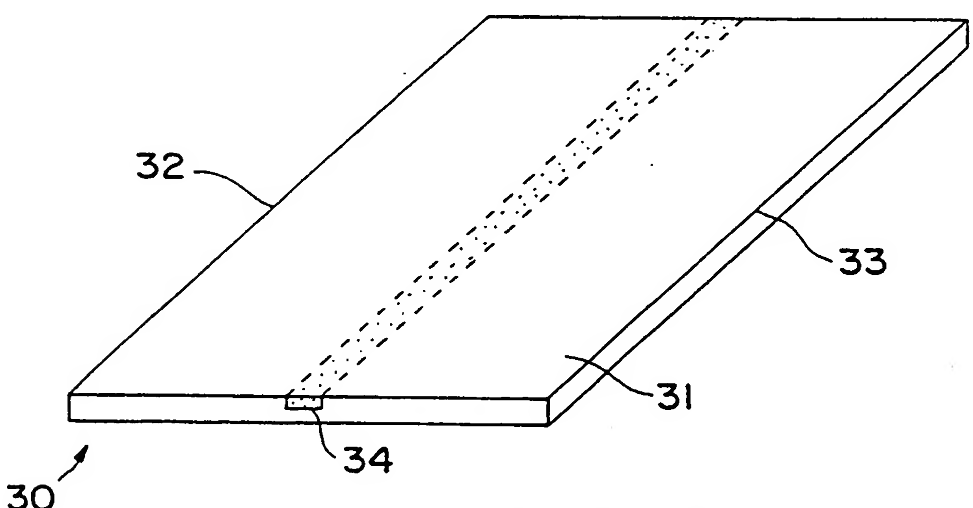

FIG. 3

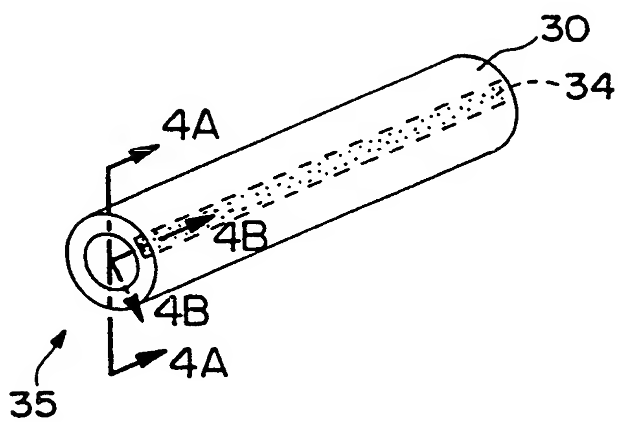

FIG. 4

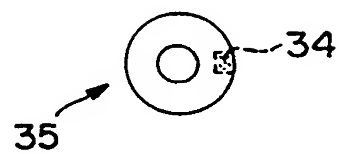

FIG. 4A

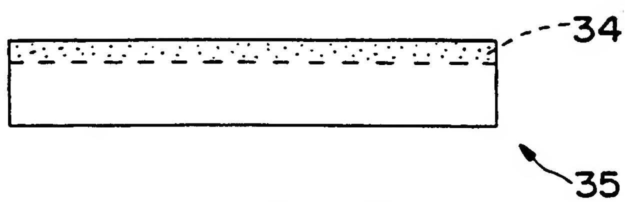

FIG. 4B

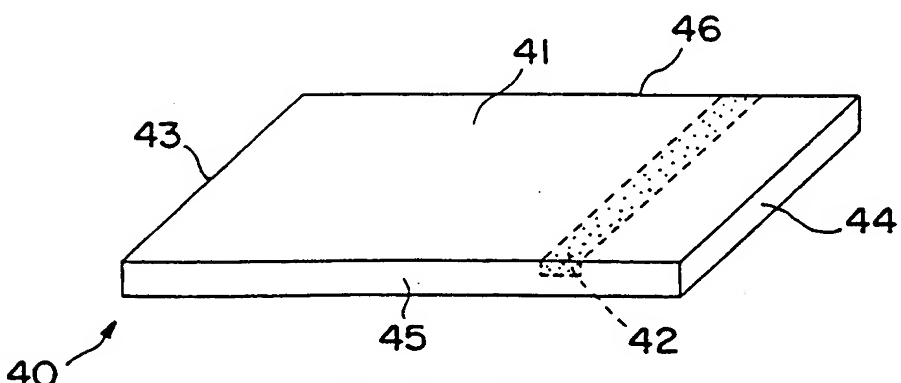

FIG. 5

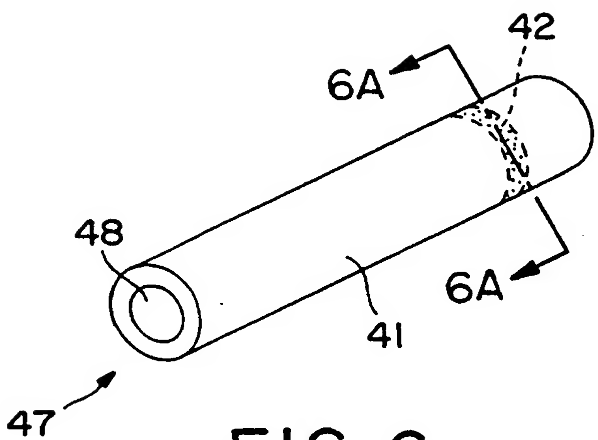

FIG. 6

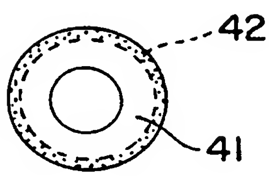

FIG. 6A

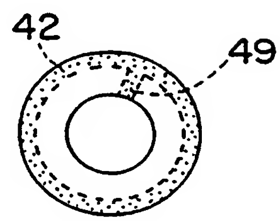

FIG. 6B

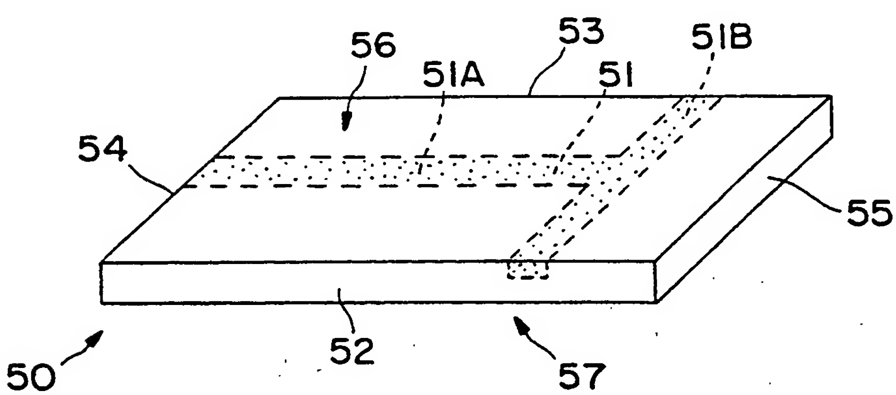

FIG. 7

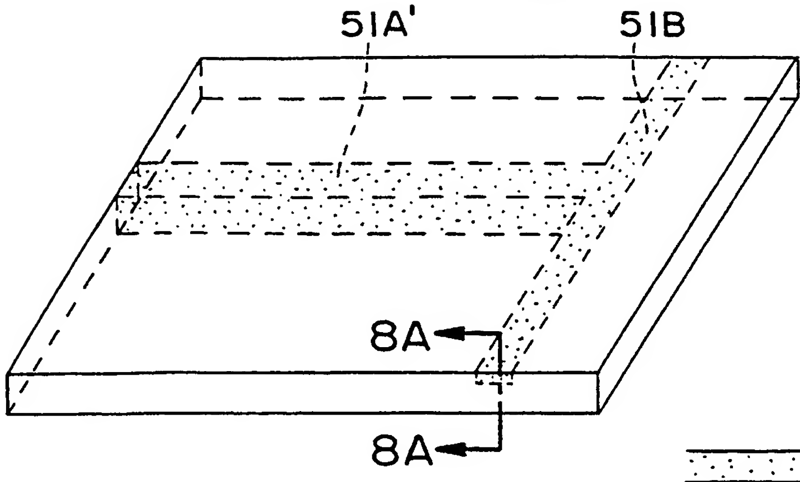

FIG. 8

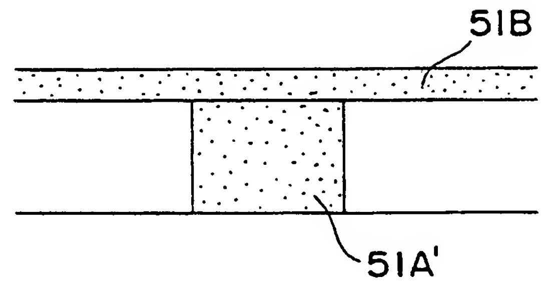

FIG. 8A

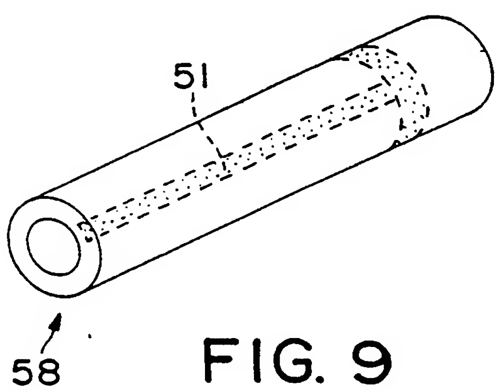

FIG. 9

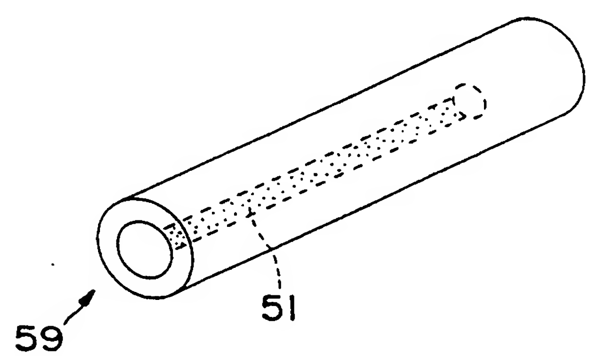

FIG. 9A

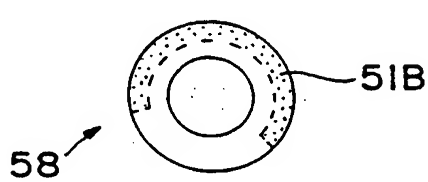

FIG. 9B

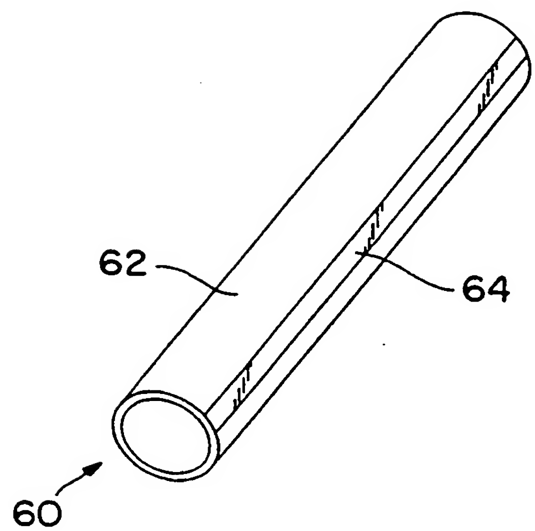

FIG. 10

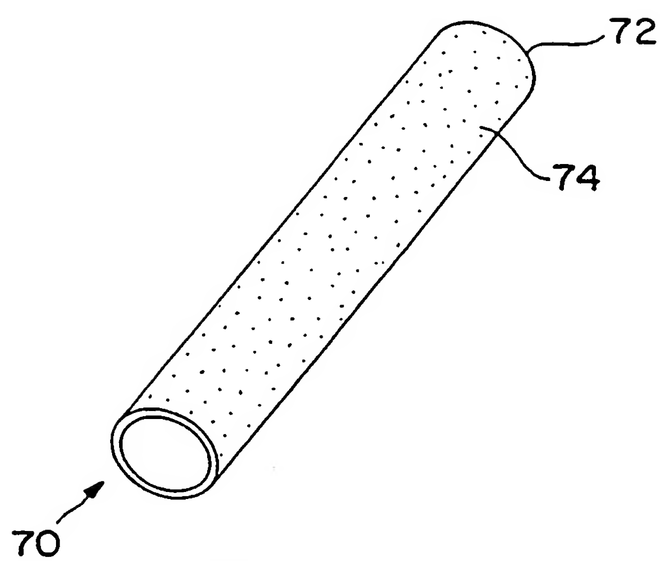

FIG. 11

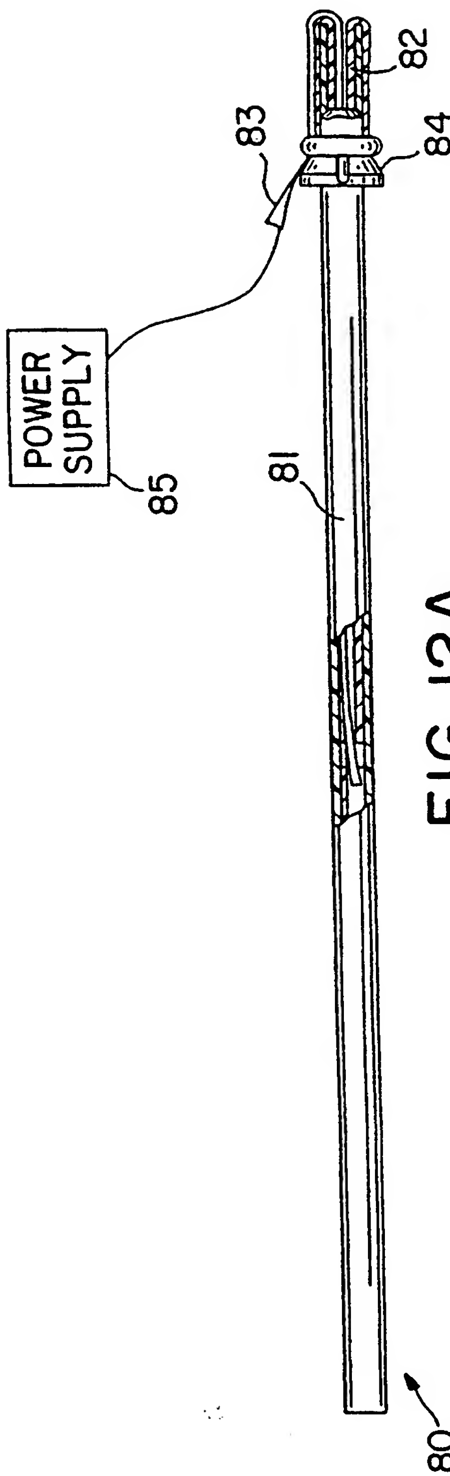

FIG. 12A

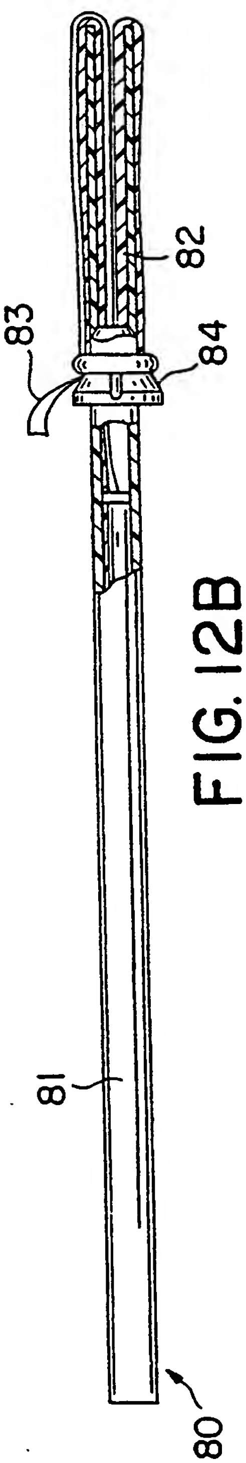

FIG. 12B

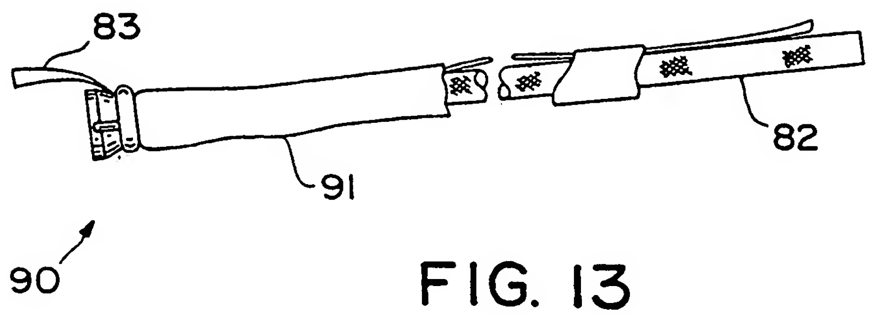

FIG. 13

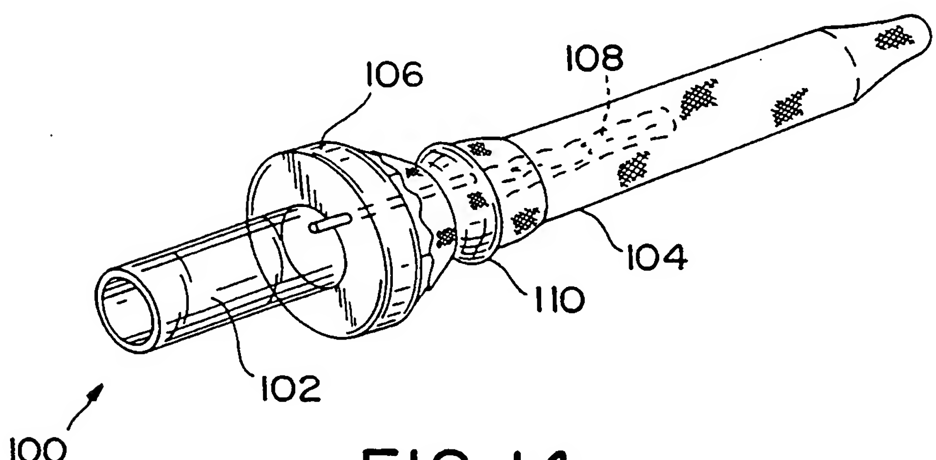

FIG. 14

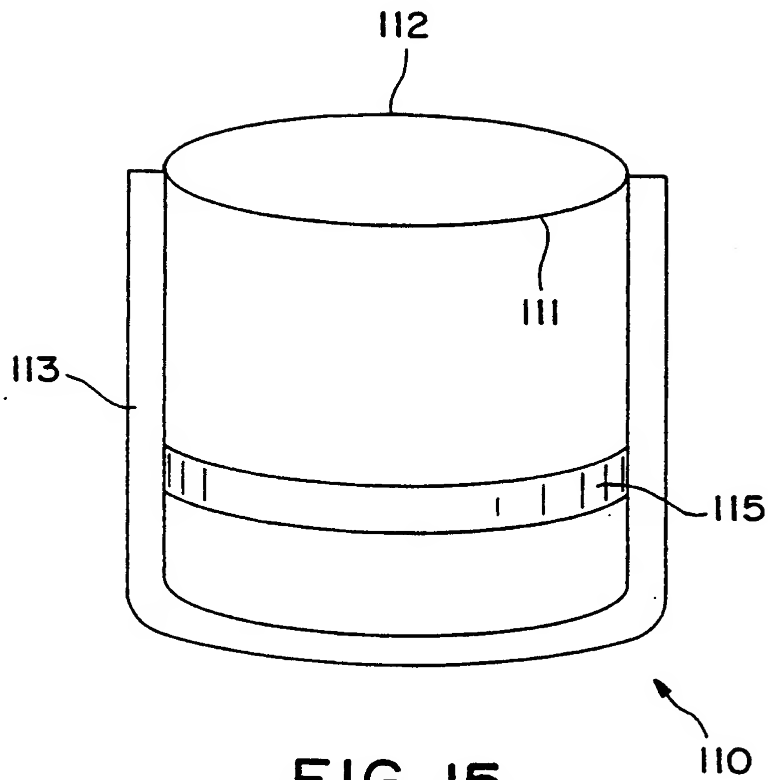

FIG. 15

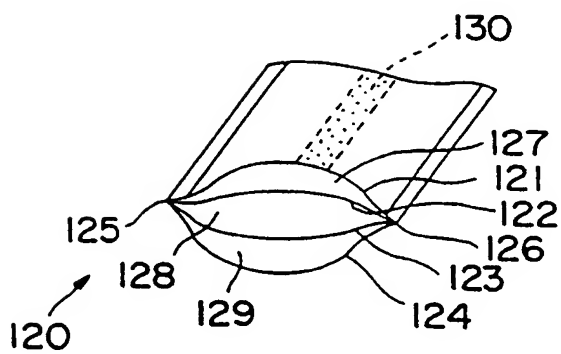

FIG. 16

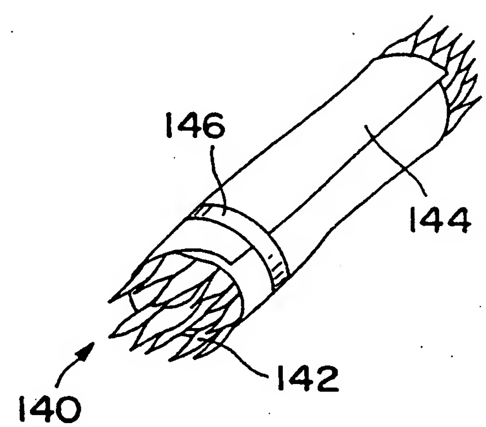

FIG. 17

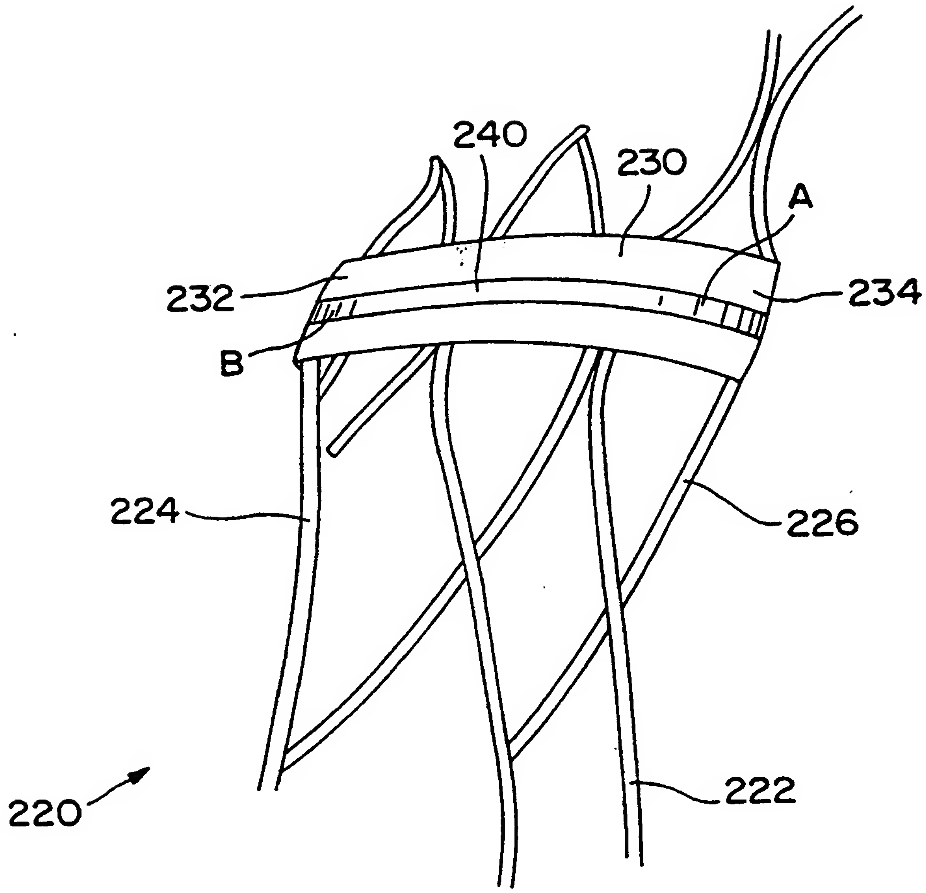

FIG. 18

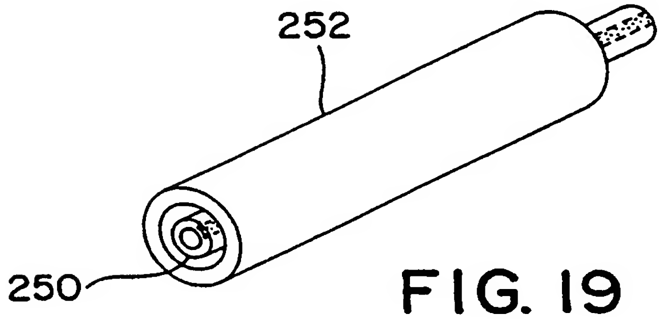

FIG. 19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/10134

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61N 1/04
US CL :607/115
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 600/372-374; 607/115, 116

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,411,527 A (ALT) 02 May 1995, entire document.	1, 4, 5, 7, 10, 11
A	US 5,044,375 A (BACH, JR. et al) 03 September 1991, entire document.	1
A	US 5,674,272 A (BUSH et al) 07 October 1997, entire document.	1, 2

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search 29 JULY 1998	Date of mailing of the international search report 08 SEP 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer SCOTT GETZOW Telephone No. 703-308-2997